DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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WO66-G609
Silver Spring, MD 20993-0002

August 21, 2014

Galt Medical Corp.
David Derrick
Director of Quality and Regulatory Affairs
2220 Merritt Dr.
Garland, TX 75041 US

Re: K140028
Trade/Device Name: VTI Valved Tearaway Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 10, 2014
Received: July 14, 2014

Dear Mr. David Derrick,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) number (if known): K140028

Device Name: **VTI®** Valved Tearaway Introducer

Indications for Use:

The introducer system is intended for use in percutaneous procedures to introduce catheters and other intravascular devices into the peripheral vasculature.

Prescription Use X (Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date Prepared:	January 02, 2014
Device Name:	VTI® Valved Tear Away Introducer
Device Model Number:	TBD
Classification Name:	Catheter Introducer (DYB), 21 CFR 870.1340
Device Classification:	Class II (Cardiovascular)
Predicate Device:	Galt VTI® Valved Tearaway Introducer Sheath, K112398 6F-16F
Manufacturer:	Galt Medical 2220 Merritt Drive Garland, TX 75041
Establishment Registration Number:	1649395
Official Contact:	David Derrick Director of Quality and Regulatory Affairs Galt Medical Corporation 2220 Merritt Dr. Garland, TX 75041 Phone: 214-778-1306 Fax: 972-271-4706 dderrick@galtmedical.com

Intended Use: The introducer system is intended for use in percutaneous procedures to introduce catheters and other intravascular devices into the peripheral vasculature.

Device Description: The finished device is a valved tear-away introducer for use in percutaneous procedures to introduce or position catheters or other interventional devices into the peripheral vasculature. The unmodified predicate introducers are constructed using identical processes and material with the exception of the subject device was modified to add a new valve design and material. The performance characteristics to the current marketed predicate device are unchanged and are consistent with other legally marketed devices.

Comparison of Technological Characteristics: The Galt VTI® Valved Tearaway Introducer is substantially equivalent to the unmodified predicate in construction, materials, and device performance.

	Subject device	Predicate Device
Mfr. / Product	**Galt VTI® Valved Tearaway Introducer with Modified Valve**	**Galt VTI® Valved Tearaway Introducer**
510(k) Number	NA	K112398
Device Classification	870.1340	870.1340
Product Code	DYB	DYB
Intended use	The introducer system is intended for use in percutaneous procedures to introduce catheters and other intravascular devices into the peripheral vasculature.	The introducer system is intended for use in percutaneous procedures to introduce catheters and other intravascular devices into the peripheral vasculature
Design	Tear-away introducer with winged sheath hub and locking dilator including an integral valve to reduce leakage and air embolism during device exchanges	Tear-away introducer with winged sheath hub and locking dilator including an integral valve to reduce leakage and air embolism during device exchanges
Color	Gray cannula with color coded hub	
Shape	Cylindrical cannula with winged hub	
Sizes	13cm, and 23cm lengths, sizes 6F – 16F	

Use Type: The Galt VTI® Valved Tearaway Introducer is a single patient use, disposable device.

Summary of Non-Clinical Data Submitted: Functional testing on un-aged and 4 year aged product was conducted to verify that the modified Galt VTI® Valved Tearaway Introducer met product specifications. Testing was conducted according to protocols based on international standards and Galt Medical requirements. Functional Testing included the following:

- Dilator lock Test
- Cap Retention Test
- Pressure Leak Test
- Vacuum Leak Test
- Prolonged Insertion Test
- Valve Separation Test
- Insertion / Extraction Test

Additionally the modified Galt VTI® Valved Tearaway Introducer was adopted into the existing ethylene oxide sterilization cycle for the Galt VTI® Valved Tearaway Introducer Sheath cleared under K112389.

Biocompatibility testing was provided in K112398. The devices tested under K112398 included identical raw materials and package configuration and materials utilized in the Galt VTI® Valved Tearaway Introducer with the exception of the new valve design. Additional biocompatibility testing that includes the material utilized to manufacture new valve design was performed and is included in this 510(k) submission.

Packaging shelf life testing was provided in K112398.

Conclusion: It has been shown in this 510(k) submission that the differences between the modified Galt VTI® Valved Tearaway Introducer and the predicate device do not raise any questions regarding safety and effectiveness. The modified Galt VTI® Valved Tearaway Introducer as designed and manufactured is determined to be substantially equivalent to the referenced predicate device.

End of Section